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10/577,781	06/22/2006	Masayoshi Yamaguchi	4439-4042	9751

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,781	YAMAGUCHI, MASAYOSHI	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 8-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/06,04/28/06,07/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to restriction requirements of October 30, 2007, has been entered. Claims 1-16 are presently pending. Applicant's election of Group I drawn to claims 1-7 is acknowledged. Applicant's election of the following species, as recited in claim 2, is acknowledged "At the stage of senility, exhibiting symptoms of hyperlipemia and/or hyperalbuminemia". Claims 4, 8-16 have been withdrawn by Applicant's amendment filed on 10-30-2007 as being directed to non-elected invention pursuant to 37 CFR1.14(b), there being no allowable generic or linking claim. There was not an election of species in the restriction requirements filed on 10-30-2007, as applicants appear to indicate for species of elected Group I, in their response filed on 11-30-2007. Therefore claims 2 and 3 are examined together as examination beyond one specific species will not impose a serious burden in the examiner. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election was treated as an election without traverse (MPEP § 818.03(a)).

The requirement is deemed proper and is therefore made FINAL.

Therefore claims 1-3 and 5-7 are currently under examination to which the following grounds of rejection are applicable.

Priority

Applicants' claim of priority to the Japanese Patent 2003-374098 published on 11-04-2003, is acknowledged. It is further noted that a certified non translated copy of the priority document was filed on 04-28-2006.

Information Disclosure Statement

The information disclosure statement filed 04-28-2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Only legible copies of non-patent literature provided in the instant application are considered. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Those citations not considered by the examiner will have a line drawn through the citation and citations considered will have the examiner's initial adjacent thereto. A submission of a legible copy of each cited non-patent literature publication or that portion which caused it to be listed is required for examination.

In the instant case, the following reference has not been submitted: JP 07-123985. The following references: JP 10-026623A, and JP 2003-164238 cited in the IDS filed on 04-28-2006, and JP 2002-177666 cited in the in the IDS filed on 07-11-2007 have been considered to the extent that an English abstract of the publication was provided.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 2-3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language.

Claims 2-3 and 5-7 use parentheses to comment on or qualify part of the sentences. It is unclear whether the limitations in parentheses are meant to be limitations in the claims or whether they are only suggestions/examples. As such, the metes and bounds of the claims cannot be determined.

Additionally, claim 2 recites the phrase "stage of senility (advanced age)" and claim 3 recites "non-human animal (female) until it exhibits a symptom of hyperalbuminemia". At page 14, paragraph [0021], the as-filed specification discloses the meaning of "advanced aged "as "can be exemplified by 30 weeks of age or older, preferably, 36 to 50 weeks of age. In case of female transgenic rats, elevated level of serum albumin concentration is observed in rats that are 25 weeks of age or older". However, significant elevation in serum lipid concentration is disclosed in female rats that are 14 weeks of age (p. 25, paragraph [0040]). Hence it is unclear whether the advanced age is defined as elevated levels of triglyceride, HDL-cholesterol, and albumin in the overexpressing regucalcin transgenic rat or its association with a defined period of age in the rats. As such, the metes and bounds of the claimed cells cannot be determined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a transgenic rat comprising in its genome a transgene comprising the rat regucalcin cDNA homozygously, wherein the transgenic rat overexpresses regucalcin, and shows at the stage of about 36 weeks to 50 weeks an increase in one or more of serum free fatty acid, triglyceride, HDL-cholesterol, free cholesterol and serum albumin,

does not reasonably provide enablement for claims directed to a transgenic, non-human animal that overexpresses regucalcin and is a model for hyperlipemia and/or hyperalbuminemia

The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to use the invention commensurate in scope with this claim. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The present invention is broadly directed to generic transgenic non-human animals wherein a nucleotide sequence has been introduced to overexpress regucalcin.

The specification discloses on pages 19-22, the generation of a transgenic rat overexpressing regucalcin as a tool for to obtain fundamental knowledge of the onset mechanisms of hepatic diseases and hyperlipemia at the stage of advanced age. Additionally the

specification contemplates a method for using the transgenic animal model for the development of preventive/therapeutic drugs for diseases showing clinical examples of hyperlipemia and hyperalbuminea (p. 27, paragraph [0047]). The claims when given the broadest reasonable interpretation encompass any non-human animal (e.g., geese, monkeys, donkeys, snails, salamanders, frogs, bumble bees and salmon) that overexpressed regucalcin and shows any pathology associated with hyperlipemia and/or hyperalbuminemia. Further the claims provides for a genus of unspecified variants of phenotypes overexpressing regucalcin in transgenic animals as a tool for hyperlipemia and/or hyperalbuminea research. Moreover, the transgenic animals are made with the contemplated use of screening for drugs useful in prevention or treatment of diseases associated with hyperlipemia and hyperalbuminea. Specific considerations for generation of a transgenic non-human mammal efficiently overexpressing a regucalcin protein such as the generation of any transgenic animal other than mice, the fate of the targeting vector in relation to a particular disruption of a gene for insertion of the target vector, and elements of a particular construct able to induce successful expression of the transgene for an expected phenotype have to be addressed for a genus of variants of phenotypes associated with a overexpressing regucalcin expression in transgenic cells. The detail of the disclosure provided by the Applicant, in view of the prior Art, must encompass a wide area of knowledge to enable one of ordinary skill in the art at the time of the invention to practice the invention without undue experimentation. However, as it will be discussed below this undue experimentation has not been overcame by the as-filed application. Though Applicant's specification teaches the generation of a transgenic rat overexpressing regucalcin exhibiting hyperlipemia at week 14 of age or older , and hyperalbuminea particularly in female rats at 36 weeks old of age or older (p.

23, Table 1, paragraph [0036]), the broad aspects of a genus of unspecified transgenic animals as well as variants for phenotypes associated with transgenic rats overexpressing regucalcin, is not reasonably enable for the full scope embraced by the claims.

In relation to the generation of any transgenic animal, the art recognize only the mouse as a routinely manipulated animal in the field of transgenics; moreover, the art recognize the unpredictability of making transgenic animals other than mice. For example, Moreadith et al., (1997, J Mol Med pp. 208-216) teaches that several putative ES cells lines have been isolated from hamster, pig, sheep, cattle, rabbit, rat, mink, monkey and humans, but the technology was limited to mice (page 214, col. 1, paragraph 3, lines 5-12). In addition, Houdebine et al., (2002, Journal of Biotechnology, Vol. 98, p. 145-160) points out that reintegration of an isolated gene into the genome of an animal by gene microinjection may generate complex and unpredictable biological situations (p. 146, first paragraph). Houdebine states that "animal transgenics is still suffering from technical limitations" (e.g., abstract). "Gene replacement by homologous recombination in somatic mammalian cells has relatively poor efficiency and "For unknown reasons, homologous recombination is more frequent in pluripotent embryonic cells" (p. 148, column 1). Post filing art by Keefer et al., (2004, Animal Reproduction Science, pp. 5-12) brings similar insight into the lack of predictability of generating any transgenic animal as he recognizes the inefficiency of pronuclear microinjection in transgenic techniques and the unpredictability of transgene expression when applied to generating cows, goats and sheep (p.6, last paragraph bridging to p. 7, paragraph 1). Thus, the art of record does not provide enablement for the claimed invention of making and using any transgenic animal other than mice.

In so far as the integration of the transgene into the target genome, the art teaches the

unpredictability of generating transgenic animals resulting with a predictable phenotype. While the art of transgenic is such that one of skill in the art would be able to produce a transgenic rat comprising a transgene of interest, it is not predictable if the transgene would be able to be expressed at a level and specifity sufficient to cause a particular phenotype. For example, transgenic animals have evolved within their cells cellular mechanisms which prevents the expression of the transgene, such as DNA methylation or deletion from the genome (1992, Kappell et al., Current Opinions in Biotechnology, p. 549, col. 1 and 2). On the other hand, the integration of a transgene into different species of animals does not always provides a model for study of a disease as the transgenic animals may not express a transgene at sufficiently levels resulting in divergent phenotypes (Mullins et al., 1993, Hypertension p. 631, col. 1, paragraph 1). To wit, Kolb et al., (1999, Gene 227:21-31; Abstract) teaches that "the expression of foreign genes in transgenic animals is generally unpredictable as transgenes integrated at random after pro-nuclear injection into fertilized oocytes" because of inhibition by neighboring chromatin. Additionally, factors influencing low gene expression, or their lack there of, are not affected by copy number and such effects are seen in lines of transgenic mice made with the same constructs (Cameron, 1977, Mol Biotechnol :253-65; page 256, col. 1-2). These factors, thus, are copy number independent and integration site dependent, emphasizing the role the integration site plays on expression of the transgene (Cameron, 1977, page 256, col. 1-2; Houdebine et al.,1994, J. Biotechnology 269-287; p. 277, col. 1, paragraph 2).

In addition to the criticality of the site of integration of a vector into a host genome, the unpredictability of a phenotype in a transgenic animal may is the result animals' genetic background. For example, Sigmund et al., (2000, Arterioscler. Thromb. Vasc. Biol., p. 1425-

1429; Abstract) reports that variation in the genetic background contributes to the unpredictability of the resulting phenotypes of transgenic or gene-targeted animals by stating "animals containing the same exact genetic manipulation exhibit profoundly different phenotypes when present on diverse genetic backgrounds, demonstrating that genes unrelated, per se, to the ones being targeted can play a significant role in the observed phenotype" (Abstract). Moreover, the same author states "many of the phenotypes examined in transgenic and knockout models are influenced by the genetic background in which they are studied...Although all mouse strains contain the same collection of genes, it is allelic variation...and the interaction between allelic variants that influence a particular phenotype. These "epigenetic" effects can dramatically alter the observed phenotype and therefore can influence or alter the conclusions drawn from experiments" (Sigmund, C., et al., 2000, p. 1425, col. 1, paragraph 1).

In addition the elements of a particular construct used to make transgenic animals are held to be critical and they must be designed case by case without general rules to obtain good expression. For example, the individual gene of interest, promoter, enhancer, coding, or non-coding sequences present in the transgene construct, the vector used, and the specific site of transgene integration into the genome (positional effect) are all important factors in controlling the expression of a transgene in the production of transgenic animal which exhibits a resulting phenotype (1994, Houdebine J. Biotech, pp. 269-87). Mullins et al., (1996, J of Clin Invest , pp.1557- 1560) discloses "the use of non-murine species for transgenesis will continue to reflect the suitability of a particular species for the specific questions being addressed, bearing in mind that a given constructs may react very different from one species to the another" (p. 1559, col. 2,

last paragraph). These issues become even more complicated when working with more than one transgene, especially when the products of one transgene regulate the expression of the other. The complex problems associated with transgenesis are illustrated by Houdebine et al., (2000, Transgenic Research, 9:305-320; pp. 309, col. 2) who states that "numerous experiments have shown that the level and specificity of expression of a gene construct used as a transgene cannot be easily predicted". Moreover, Houdebine et al. discloses that the potency of any transgene can only be estimated in transgenic animals and the level of expression of transgenes in mice is not predictive of their levels in other animals (pg. 310, col. 1, paragraph 2). Finally, Houdebine et al. states that another well known problem with transgenesis is leaky expression of the transgene in various tissues in which the utilized promoter is not expected to work because of ectopic expression due to a position effect (pg. 310, col.1, paragraph 3). Murray (1999, Theriogenology , 51:149-159; p. 150, paragraph 4) further confirms the unpredictability of using the same construct in different species when he states, "the observation that the oMT1a-oGH transgene that is regulated in mice is uncontrollable in both sheep and pigs suggests that transgene constructs still need to be tested in the species of interest."

Alternatively, the claims may be interpreted to read on somatic cell gene transfer. The claims, as written, do not specifically convey germline transmission of the transgene and could also be interpreted as one cell in any non-human transgene animal that have been transformed with a vector comprising a nucleic acid molecule encoding a regucalcin having a single cell expressing said protein. It would be unpredictable if expression of said transgene in a single cell of a transgenic non-human would result in collectable amount of the polypeptide of as to be overexpressed . Moreover, when interpreting the cells as somatic cell gene transfer the claims

could also embrace both tissue/cell specific and/or systemic specific polypeptide expression depending on which promoter is used. The prior art in fact teaches that foreign genes can be expressed by transfecting mammalian cells with a variety of vectors driving the expression of a foreign gene in organs as in the case of the human growth hormone under the control of a strong promoter (e.g., metallothionein gene) wherein the transgene is expressed at high rate in many tissues, however most of the therapeutic proteins generated are unstable and are rapidly cleared from the circulation (Houdebine, J. of Biotechnology, 1994, 269-287; p. 271, col. 2). Therefore it would be unpredictable if transgenic non-human mammals created by somatic cell gene transfer to any cell could be created and used in accordance with the invention as claimed.

The specification discloses the generation of a transgenic rat carrying the cDNA homozygously that were raised to 36 weeks of age (p. 20, [0032]). Moreover, the transgenic rats that were dissected, their blood was collected, and their femoral tissues were extracted to measure bone calcium content by atomic absorbance as well as serum components (p. 21, [0033]). The specification teaches different serum concentrations of calcium, inorganic phosphorus, zinc, glucose, triglyceride, HDL-cholesterol, and albumin, according to the types of rats, transgenic rats (homozygotes) or wild-type rats, and to the sex (p. 22, [0034]). For example, at 36 weeks of age, regucalcin transgenic rats develop bone lost (p. 23, [0037]). In relation to serum components, results indicated age related changes for 14-, 25-, 36-, 50-week-old regucalcin transgenic rats. For example, serum lipid concentrations (e.g., free fatty acid, triglyceride, HDL-cholesterol, free cholesterol) was observed in female rats that were 14 weeks of age or older, and that the elevation was significant in 50-week-old (1-year-old) rats (p. 25, [0040]). Moreover, the specification contemplates the use of the regucalcin transgenic non

human animals in prevention or treatment of diseases associated with hyperlipemia and hyperalbuminea other than regucalcin transgenic rats (p. 27, [0047]). However, the specification provides neither guidance nor working examples for the generation of any transgenic non-human animal comprising a nucleotide sequence overexpressing regucalcin so as to successfully exhibit a symptom of hyperlipemia and/or hyperalbuminemia. Further, the specification fails to provide any evidence that the claimed transgenic non-human animals would respond differently than a wild-type non-human animal in the development of any preventive/therapeutic drugs for diseases related to hyperlipemia and hyperalbuminea.

As set forth above by the nature of the invention given such species differences (e.g., primates, cattle, rabbits) in the expression of a transgene, neither the prior art of record nor the as-filed specification provides sufficient guidance to enable a person skilled in the art to generate any non-human transgenic animal overexpressing regucalcin. Even assuming the generation of a transgenic rat, the specification fails to provide teachings or specific guidance to overcome the above described unpredictability (e.g., the fate of the targeting vector in relation to a particular disruption of a gene for insertion of the target vector, elements of a particular construct to induce efficient expression of the transgene, leaky expression of the transgene in various tissues in which the utilized promoter is not expected to work because of ectopic expression due to a position effect), in order to successfully carry out the claimed regucalcin transgenic non human animals and as such, the claims are not enabled. Thus, given the unpredictability of the art and the lack of working example in the instant specification, particularly when taken with the lack of guidance in the specification, it would have required undue experimentation to practice the instant method to identify an enormous number of transgenic non-human animals as broadly or

generically claimed.

Claim Rejections - 35 USC § 102(b)

To the extent that the instant claims embrace a transgenic rat model comprising a regucalcin gene overexpressing said protein the following rejections apply.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamaguchi et al. (Published on-line June 24, 2002; J. Cell. Biochem 86:520-529). Yamaguchi et al., is considered proper prior art as the inventive entity of the Yamaguchi et al., reference is different from that of the instant application. The only shared inventor between the two is Masayoshi Yamaguchi.

Yamaguchi et al. teaches the generation of regucalcin transgenic rats with remarkable expression of regucalcin (Abstract). Moreover, Yamaguchi et al. discloses that a DNA fragment containing the regucalcin gene in pCXN2 was used for pronuclear microinjection of SD rat embryos to generate transgenic rats. Claims 1 and 6.

The founder rats were mated to produce F1 liters. Male and female heterozygote rats were identified and bred to homozygosity (pg. 521, col. 2, paragraph 2). Claim 5.

Although, Yamaguchi et al. discloses that both 5-week-old homogeneous transgenic rats male and female showing prominent expression of regucalcin (p. 523, col. 2, paragraph 1) did

not exhibit any significant difference in levels of triglyceride, free cholesterol and albumin, the structure of the regucalcin transgenic rat is identical to the one instantly claimed and therefore the phenotypes at any age are inherently the same (see Table I at page 528). Claims 2, 3 and 7.

Please note that "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or *In re Best*, 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

Therefore , Yamaguchi et al., teaches all the claimed limitations and anticipates Applicant's claimed invention

Claim Rejections

Provisional Rejection, Obviousness Type Double Patenting-No secondary Refence(s)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 2 and 5-7 are provisionally rejected on the ground of nonstatutory double patenting over claims 25, 27, 28, 29, 30 and 33 of copending Application No. 10/804,515. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The subject matter of the instant application has been discussed previously in this Office Action (see above sections). Application 10/804,515 is drawn to a transgenic rat comprising in its genome a transgene comprising the rat regucalcin cDNA homozygously, wherein the transgenic rat overexpresses regucalcin, and shows at decrease in bone density, or bone strength or bone thickness of diaphyseal cortex or length of surrounding cortex. The as filed specification teaches that the transgenic non human animals exhibits not only significant and marked increase of serum albumin, HDL-cholesterol and triglyceride concentrations but also bone disorders including bone loss and decreased bone density (p. 5, paragraph [0008]). Therefore, the claims of the instant application supported by the disclosure of the specification and those of Application No. 10/804,515 are not obviously distinct from each other.

Because claims 1, 2 and 5-7 of the instant invention are broadly drawn to a transgenic non-human animal model, claims 1, 2 and 5-7 embrace claims 25, 27, 28, 29, 30 and 33 as set forth in the copending application copending Application No. 10/804,515.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1, 2 and 5-7 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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